The Honorable Tana Lin

UNITED STATES DISTRICT COURT
WESTERN DISTRICT OF WASHINGTON
AT SEATTLE

UNITED STATES OF AMERICA, Plaintiff, vs. DIANE LOUISE ZOLLINGER, an individual, doing business as FELIX CUSTOM SMOKING, a sole proprietorship. Defendant.	Case No.: 22-cv-00278-TL **~~[PROPOSED]~~ ORDER OF PERMANENT INJUNCTION**

Plaintiff, the United States of America filed a Complaint for Permanent Injunction against Diane Louise Zollinger, an individual doing business as Felix Custom Smoking (Defendant). Defendant was served, but did not answer the Summons or appear before the Court, and accordingly, default judgment is entered on behalf of Plaintiff;

IT IS HEREBY ORDERED AND ADJUDGED that:

1. This Court has jurisdiction over the subject matter and all parties to this action under 28 U.S.C. §§ 1331 and 1345, 21 U.S.C. § 332, and its inherent equitable authority.

2. The Complaint states a cause of action against Defendant under the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. §§ 301 *et seq.* (the "Act").

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3. Defendant violated the Act, 21 U.S.C. § 331(k), by causing articles of food within the meaning of 21 U.S.C. § 321(f), namely fish and fishery products, to become adulterated within the meaning of 21 U.S.C. § 342(a)(1) and (4), in that they had been prepared, packed, or held under insanitary conditions whereby they may have become contaminated with filth or may have been rendered injurious to health, while such articles are held for sale after shipment in interstate commerce.

4. Upon entry of this Order, Defendant and each and all of her directors, officers, agents, representatives, employees, attorneys, successors and assigns, and any and all persons or entities in active concert or participation with her (including individuals, partnerships, corporations, subsidiaries, affiliates, franchisees, and "doing business as" entities) (hereinafter, collectively referred to as "Associated Persons"), who receive actual notice of this Order by personal service or otherwise, are permanently restrained and enjoined under the provisions of 21 U.S.C. § 332(a) and the inherent equitable authority of this Court, from directly or indirectly receiving, preparing, processing, packing, labeling, holding, and/or distributing any article of food at or from the facility located at 17461 147th Street Southeast Suite 2A, Monroe, Washington, or any other location(s) at which Defendant now or in the future directly or indirectly receives, prepares, processes, packs, labels, holds, and/or distributes articles of food (referred to as "the Facility") unless and until:

A. Defendant retains, at her expense, an independent laboratory (the "Laboratory") having no personal or financial ties (other than the retention agreement) to Defendant or her families, and that is qualified to analyze product and environmental samples collected at the facility for the presence of all *Listeria* species, including *Listeria monocytogenes*, in a manner that is acceptable to the United States Food and Drug Administration ("FDA"). Defendant shall

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notify FDA in writing within three (3) business days of retaining the Laboratory and shall provide FDA a copy of the service contract. Such service contract shall contain provisions, acceptable to FDA, for environmental and finished product sample analyses; and

B. Defendant retains, at her expense, an independent expert or experts (the "Expert(s)") having no personal or financial ties (other than a retention agreement) to Defendant or her family, and who, by reason of background, education, training, or experience, is qualified to:

(1) Conduct hazard analyses to develop adequate Hazard Analysis Critical Control Point ("HACCP") plans for Defendant's fish and fishery products, as required by 21 C.F.R. § 123.6;

(2) Verify and ensure the adequacy of Defendant's HACCP plans in accordance with paragraphs 4(C)(1-3) below;

(3) Develop procedures for processing Defendant's fish or fishery products to achieve water phase salt levels that adequately control *Clostridium botulinum* in all of Defendant's reduced oxygen packaged smoked fish or fishery products and to achieve water activity levels that adequately control *Clostridium botulinum* in all of Defendant's dried fish or fishery products;

(4) Develop adequate written Sanitation Standard Operating Procedures ("SSOPs") in accordance with paragraph 4(C)(5) below;

(5) Develop a *Listeria* Monitoring Program in accordance with paragraph 4(C)(6) below;

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(6) Collect product and environmental samples from within the facility for pathogen testing, water phase salt level testing, and water activity testing in accordance with paragraph 4(C)(7) below;

(7) Evaluate Defendant's compliance with the current good manufacturing practice ("cGMP") requirements as required by 21 C.F.R. Part 117;

(8) Develop and conduct employee training programs (in English and any other language necessary to effectively convey the substance of the training) on the SSOPs, seafood HACCP and cGMP requirements, and *Listeria* Monitoring Program; and

(9) Inspect the facility and determine whether the methods, facilities, and controls are operated and administered in conformity with the Act, its implementing regulations, and this Order; Defendant shall notify FDA in writing of the names(s) and qualifications of the Expert(s) under paragraph (B) within three (3) business days of retaining such Expert(s);

C. After reviewing all FDA inspectional observations of deficiencies from August 2018 to the present, and after consultation with the Laboratory, Defendant's Expert(s), in conjunction with Defendant:

(1) Conducts hazard analyses and develops, to FDA's satisfaction, an adequate written HACCP plan, as required by 21 C.F.R. § 123.6, for each type of fish and/or fishery product received, prepared, processed, packed, labeled, held, and/or distributed by Defendant, that at a minimum, effectively controls food safety hazards, including but not limited to (i) those associated with *Clostridium botulinum* growth and toxin formation likely to occur in reduced oxygen packaged fish and fishery products under normal and moderate temperature abuse conditions; and (ii) those associated with pathogen growth and toxin formation in ready-to-eat fish and fishery products.

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(2) Provide evidence of the adequacy of the critical limits listed in Defendant's HACCP plan to control *Clostridium botulinum* growth and toxin formation in Defendant's reduced oxygen packaged fish and fishery products, and dried fish and fishery products. Such evidence shall include, at a minimum, scientific evidence that the critical limits listed in Defendant's HACCP plan are adequate to ensure that Defendant's finished products achieve a water phase salt level of 3.5% or higher for the reduced oxygen packaged smoked fish and fishery products or a water activity level of 0.85 or less for the dried fish and fishery products;

(3) Develops, to FDA's satisfaction, written corrective action plans as part of Defendant's HACCP plans to be taken whenever there is a deviation from a critical limit, as described in 21 C.F.R. § 123.7(b);

(4) Develops, to FDA's satisfaction, written verification procedures as part of Defendant's HACCP plans, as described in 21 C.F.R. §123.8;

(5) Develops, to FDA's satisfaction, written SSOPs specific to Defendant's facility and operations and shall conform with the procedures set forth at 21 C.F.R. § 123.11(a) through (d), and ensures, to FDA's satisfaction, that Defendant's operations comply with the Act and 21 C.F.R. Part 117;

(6) Develops and implements, to FDA's satisfaction, a written *Listeria* Monitoring Program that shall include, at a minimum, the following:

(a) an effective written sanitation control program that establishes adequate methods, processes, and controls for receiving, preparing, processing, packing, labeling, holding, and distributing articles of food to minimize the risk of introducing *Listeria monocytogenes*, other pathogenic organisms, and filth into Defendant's food, and to ensure that foods are not adulterated within the meaning of 21 U.S.C. § 342(a). Such methods, processes,

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and controls shall include, but shall not be limited to, thoroughly cleaning, sanitizing, renovating, and rendering the facility and all equipment therein suitable for use in receiving, preparing, processing, packing, holding, and/or distributing food to prevent it from becoming adulterated, and ensuring that the facility and all equipment therein are continuously maintained in a sanitary condition;

(b) an effective program for environmental monitoring and testing of the facility to ensure that organisms such as *Listeria* species are systemically controlled, and harborage sites are identified and eliminated, so that pathogenic organisms such as *Listeria monocytogenes* do not occur in finished products. Sampling should be conducted using specified frequencies and methods (e.g., including how, where, and when to sample; the number and frequency of samples to be collected; and the methods of analyses) that are acceptable to FDA. Environmental monitoring shall include, but shall not be limited to, collecting samples from food-contact surfaces, equipment, and other sites throughout the facility (where the raw ingredients, and in-process and finished products are received, prepared, processed, packed, held, and/or distributed, and common areas that could be reservoirs for cross-contamination), and analyzing samples in a manner acceptable to FDA. Defendant shall ensure that the results of all analyses conducted pursuant to paragraph 4(C)(6)(b) are sent to FDA within two (2) calendar days after receipt by Defendant; and

(c) an adequate written plan for remedial action that Defendant shall implement should *Listeria* species or any pathogenic organism, including *Listeria monocytogenes*, be detected. The remedial action shall include, at a minimum, product disposition, intensified sanitation, intensified sampling measures, a comprehensive investigation,

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and a contamination source determination (i.e., root cause analysis), all of which are acceptable to FDA.

(7) Develops and conducts, to FDA's satisfaction, employee training programs (in English and any other language necessary to effectively convey the substance of the training) on the seafood HACCP and cGMP regulations, FDA-approved HACCP plans, SSOPs, and *Listeria* Monitoring Program, and any other control strategies specific to Defendant's fish and fishery products, and documents that Defendant and each of her officers, employees, and any other person(s) who perform duties at Defendant's facility for Defendant have received such training; and

(8) Submits to FDA the written HACCP plans and all associated records (including monitoring records), validation studies, SSOPs, the *Listeria* Monitoring Program, written verification procedures, and training programs developed pursuant to paragraphs 4(C)(1)-(6) above; and documentation demonstrating that the Expert(s) have trained Defendant and each of her officers, employees, and any other persons who perform duties at Defendant's facility as described in paragraph 4(C)(7) above;

D. FDA has approved, in writing, the seafood HACCP plans, validation studies, SSOPs, *Listeria* Monitoring Program, written verification procedures, and employee training programs and documentation developed by the Expert(s) as specified in paragraphs 4(C)(1)-(7) above;

E. Defendant takes the following additional actions:

(1) Assigns continuing responsibility for implementing and monitoring the FDA-approved SSOPs and *Listeria* Monitoring Program to a person (or persons) who, by reason of background, education, training, or experience, is qualified to maintain Defendant's facility in

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a sanitary condition, coordinate with the Laboratory, and implement any necessary corrective action(s), and Defendant provides such person with the authority to achieve any necessary corrective action;

(2) Ensures that the FDA-approved HACCP plans, *Listeria* Monitoring Program, and SSOPs are available and accessible (in English and any other language necessary to effectively convey the substance of such documents) to her officers, employees, and any other persons who perform duties for Defendant;

(3) Successfully administers an FDA-approved employee training program; and

(4) At her expense, have the Expert(s) supervise and document intensified cleaning and sanitizing of her facility and equipment followed by environmental sampling as verification of effectiveness therein and make improvements, thereby rendering her facility and equipment suitable for receiving, preparing, processing, packing, holding, labeling, and distributing articles of food in accordance with this Order, the Act, and all applicable regulations, remedying inspectional observations from August 2018 to the present, and Defendant ensures that her facility and equipment therein will be continuously maintained in a sanitary condition.

F. The Expert(s) conducts a comprehensive inspection of Defendant's facility and the methods and controls used to receive, prepare, process, pack, label, hold, and distribute food to determine whether Defendant has effectively implemented all necessary corrections and is fully prepared to operate in compliance with this Order, the Act, and all applicable regulations. The Expert(s) shall verify, with supporting documentation, that (i) Defendant has corrected all of the seafood HACCP and cGMP deficiencies observed by FDA since August 2018, specifying each FDA observation and Defendant's corrections thereof; (ii) the monitoring equipment used to

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implement Defendant's HACCP plans is suitable and performing adequately; and (iii) Defendant's facility and the methods and controls used to receive, prepare, process, pack, label, hold, and distribute articles of food are, in the Expert's opinion, in compliance with this Order, the Act, and its implementing regulations. The comprehensive inspection shall also include, but shall not be limited to, taking environmental samples from Defendant's facility, and testing such samples in accordance with paragraph 4(C)(6)(b), identifying and eliminating harborage sites, and conducting a root cause analysis. The Expert(s) shall submit, in writing, all findings and supporting documentation to Defendant and FDA concurrently, within fifteen (15) business days after completion of the inspection;

G. Defendant reports to FDA in writing the actions she has taken to bring her operations into compliance with this Order, the Act, and its implementing regulations, including, producing documentation that Defendant has cleaned and sanitized the facility and equipment therein and made improvements, thereby rendering the facility and equipment suitable for receiving, manufacturing, preparing, processing, holding, labeling, packing, and distributing articles of food; and identifying specific measures that Defendant has taken to address each of the violations documented by FDA since August 2018;

H. Defendant destroys, under FDA's supervision, and according to a destruction plan submitted in writing by Defendant and approved in writing by FDA prior to implementation, all raw ingredients and all in-processed and finished articles of food currently in her custody, control, or possession at the time this Order is entered by the Court;

I. Defendant recalls, to the retail level, and destroys all fish and fishery products distributed to date.

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J. FDA, as it deems necessary to evaluate Defendant's compliance with the terms of this Order, the Act, and its implementing regulations, conducts inspections of Defendant's facility, including the buildings, sanitation-related systems, equipment, utensils, labeling, and all articles of food and relevant records contained therein;

K. Defendant has paid all costs of inspection, analysis, review, investigation, examination, and supervision for FDA's oversight with respect to paragraph 4(A) though (G), at the rates set forth in paragraph 12; and

L. FDA has notified Defendant in writing that Defendant appears to be in compliance with the requirements set forth in paragraphs 4(A)-(H) of this Order, the Act, and its implementing regulations. In no circumstance shall FDA's silence be construed as a substitution for written notification.

5. After receiving notice from FDA pursuant to paragraph 4(L), Defendant shall not receive, prepare, process, pack, hold, label, or distribute any fish or fishery product not identified in a written HACCP plan approved by FDA pursuant to paragraph 4(D) until Defendant submits for FDA's review a written HACCP plan for such fish or fishery product and receives FDA's written approval for such plan. In no circumstance shall FDA's silence be construed as a substitution for written approval.

6. Immediately upon resuming operations after completing the requirements of paragraph 4, Defendant shall, in consultation with the Expert(s), continuously implement the written seafood HACCP plans, SSOPs, *Listeria* Monitoring Program, written verification procedures, and employee training programs approved by FDA pursuant to paragraph 4(D). Defendant further shall comply with the following requirements:

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A. Defendant shall conduct finished product testing for water phase salt levels in the Defendant's reduced oxygen packaged smoked fish and fishery products and water activity in the Defendant's dried fish and fishery products in the following manner:

(1) Defendant shall have tested randomly collected samples taken to be a representative sample from every lot of finished fish or fishery products that she processes for the first fifteen (15) consecutive production days, and all such samples shall have a water phase salt level or water activity level that adheres to the critical limits set forth in the HACCP plans approved by FDA pursuant to paragraph 4(D);

(2) After satisfying the requirements of paragraph 6(A)(1), Defendant shall have tested randomly collected samples taken to be a representative sample from one lot of each type of finished fish or fishery products that she processes each week for the next three (3) months;

(3) After satisfying the requirements of paragraph 6(A)(2), Defendant shall have tested randomly collected samples taken to be a representative sample from one lot of each type of finished fish or fishery products she processes each month for the next twelve (12) months; and

(4) After satisfying the requirements of paragraph 6(A)(3), Defendant shall have tested randomly collected samples taken to be a representative sample from one lot of each type of finished fish or fishery products she processes every three (3) months thereafter.

(5) Defendant shall send copies of the results of the tests conducted pursuant to paragraph 6(A) to FDA within two (2) calendar days after receipt by Defendant. If any sample analysis conducted pursuant to paragraph 6(A) shows a water phase salt level or water activity level that does not adhere to the critical limits set forth in the HACCP plans approved by FDA

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pursuant to paragraph 4(D), Defendant shall immediately destroy the affected lot(s) at Defendant's expense, under FDA's supervision, and pursuant to a destruction plan approved in writing by FDA. Defendant further shall reassess her processing operations to determine the cause of the deviation, correct the deviation, revise her HACCP plan(s) accordingly, and submit such revisions for FDA's written approval. After correcting the cause of the deviation, Defendant shall reinstate the complete sequence of testing under paragraph (A) anew; and

B. Defendant shall conduct finished product testing for *Listeria monocytogenes* in the following manner:

(1) Randomly collected samples taken to be a representative sample from every lot of fish or fishery products that she processes for the first five (5) consecutive production days;

(2) After the completion of testing under paragraph 6(B)(1), Defendant shall have tested randomly collected samples taken to be a representative sample from one lot of each type of finished fish or fishery products that she processes each week for the next three (3) months;

(3) After the completion of testing under paragraph 6(B)(2), Defendant shall have tested randomly collected samples taken to be a representative sample from at least one lot of each type of finished fish or fishery products that she processes each month for the next twelve (12) months; and

(4) After completion of testing under paragraph 6(B)(3), Defendant shall have tested randomly collected samples taken to be a representative sample from at least one lot of each type of finished fish or fishery products that she processes every three (3) months thereafter.

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(5) Defendant shall send copies of the results of all testing conducted pursuant to paragraph 6(A) to FDA within two (2) calendar days after receipt by Defendant. If any laboratory test completed pursuant to paragraph 6(B) shows the presence of *Listeria monocytogenes* in any article of food, then Defendant must immediately cease production and notify FDA that production has ceased. Defendant shall also destroy, at Defendant's expense, under FDA's supervision, and according to a destruction plan submitted to and approved by FDA in writing prior to implementation, all food products manufactured from the time the laboratory sample(s) testing positive for *Listeria monocytogenes* was collected. Defendant may resume production only when she has determined and corrected the cause of the contamination and only after FDA notifies Defendant in writing that Defendant appears to be in compliance with the requirements of this Order, the Act, and its implementing regulations. After correcting the cause of the contamination, Defendant shall reinstate the complete sequence of testing under paragraph 6(B) anew; Defendant shall implement, on an ongoing basis, the *Listeria* Monitoring Program developed pursuant to paragraph 4(C) and approved by FDA pursuant to paragraph 4(D);

C. Conduct environmental monitoring and testing as set forth in paragraph 4(C)(6) to ensure that the SSOPs effectively address the *Listeria monocytogenes* hazard and that the SSOPs are consistently followed. Environmental testing shall be performed by the laboratory in accordance with timetables and methods that Defendant submits in writing to FDA for prior written approval by FDA. Defendant shall ensure that the results of all testing conducted pursuant to this paragraph are forwarded to FDA within two (2) business days after receipt by Defendant;

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D. Defendant's environmental testing shall include, at a minimum, all of the following:

(1) If a food- or non-food-contact surface tests positive for *Listeria* species during routine testing, intensified sampling must be initiated immediately, in conjunction with intensified cleaning and sanitizing. Intensified sampling requires that at least three (3) surrounding areas are sampled during production and analyzed; and

(2) Any *Listeria* species isolate from a food-contact surface must be tested further to determine whether it is *Listeria monocytogenes*. In addition, all food products that come in contact with a site that tests positive for *Listeria* species since the last cleaning and sanitizing of the affected area occurred must be held pending laboratory test results of those food products and further testing of the *Listeria* species isolate from the food-contact surface. Defendant shall submit her sampling plan for product testing to FDA, which must be acceptable to FDA prior to testing. The food products can be released only if laboratory test results for the food products are negative for *Listeria* and the food-contact surface isolate is not *Listeria monocytogenes*. If the laboratory test results for the food products or the food-contact surface are positive for *Listeria monocytogenes*, Defendant must destroy—at her own expense and under FDA's supervision, and according to a written destruction plan submitted by Defendant and approved in writing by FDA prior to implementation—all food products manufactured from the time of the last cleaning and sanitizing of the affected area occurred, the Defendant shall bear the costs of FDA's supervision of such destruction at the rates specified in Paragraph 12; and

E. In the event that Defendant or her Expert(s) determine that the *Listeria* Monitoring Program that FDA approved pursuant to paragraph 4(D) needs to be revised, Defendant shall provide proposed changes to FDA in writing at least twenty (20) calendar days prior to their

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implementation and shall not implement the proposed changes until FDA approves those changes in writing. Any such changes shall consist of methods and controls that are shown to FDA's satisfaction to systematically control *Listeria* species and ensure that *Listeria monocytogenes* does not occur in finished products.

7. Within thirty (30) calendar days after Defendant resumes her operations after completing the requirements of paragraph 4 and receiving the notice set forth in paragraph 4(L), the Expert(s) shall conduct a comprehensive inspection of the facility, and any other location(s) at or from which Defendant receives, prepares, processes, packs, holds, or distributes articles of food, and the methods and controls used to receive, prepare, process, pack, hold and distribute foods to determine whether Defendant is operating in compliance with this Order, the Act, and all applicable regulations. The Expert(s) shall submit a report documenting all findings to Defendant and FDA concurrently, within ten (10) calendar days after completing the inspection. Thereafter, the Expert(s) shall conduct one inspection every three (3) months for one year, and one inspection every six (6) months for the next two (2) years. Beginning in the fourth year after Defendant resumes her operations after completing the requirements of paragraph 4, the Expert(s) shall conduct inspections annually unless FDA informs Defendant in writing that more frequent expert inspections and reporting are required. During each inspection conducted by the Expert(s), the Expert(s) shall verify that the facility and the methods and controls Defendant uses to receive, prepare, process, pack, hold, and distribute articles of food are in compliance with the requirements of this Order, the Act, and all applicable regulations, and shall certify compliance in the Expert's report. If the Expert's report contains any observations indicating that Defendant is not in compliance with this Order, the Act, or its implementing regulations, Defendant shall

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make all necessary corrections within ten (10) business days after receipt of the Expert's report, unless FDA notifies Defendant in writing that a shorter time period is necessary.

8. All testing required pursuant to this Order shall be conducted by the Laboratory retained pursuant to Paragraph 4(A). If Defendant terminates or alters in any way her service contract with the laboratory retained pursuant to Paragraph 4(A), Defendant shall notify FDA within three (3) business days after such termination or alteration. If Defendant terminates her service contract, Defendant shall immediately retain the services of another laboratory consistent with the requirements of Paragraph 4(A). Defendant shall provide a copy of any altered or new laboratory service contract to FDA within three (3) business days after such service contract is executed.

9. Defendant and each and all of her directors, officers, agents, representatives, employees, attorneys, successors and assigns, and any and all persons or entities in active concert or participation with any of her (including individuals, partnerships, corporations, subsidiaries, affiliates, franchisees, and "doing business as" entities), who receive actual notice of this Order are permanently restrained and enjoined under the provisions of 21 U.S.C. § 332(a) from directly or indirectly doing or causing any act that:

A. Violates the Act, 21 U.S.C. § 331(k), by causing any article of food within the meaning of 21 U.S.C. § 321(f) to become adulterated within the meaning of 21 U.S.C. §§ 342(a)(1) and (4) while such article is held for sale after shipment of one or more components in interstate commerce;

B. Results in the failure to implement and continuously maintain the requirements of this Order.

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10. FDA shall be permitted, without prior notice and as and when FDA deems necessary, to inspect Defendant's facility located at 17461 147th Street Southeast Suite 2A, Monroe, Washington, or any other location(s) at which Defendant now or in the future directly or indirectly receives, prepares, processes, packs, labels, holds, and/or distributes articles of food and, without prior notice, to take any other measures necessary to monitor and ensure continuing compliance with the terms of this Order, the Act, and its implementing regulations. During such inspections, FDA shall be permitted to: (i) have immediate access to buildings and the contents therein, including equipment, raw ingredients, in-process and finished articles of food, containers and packaging material; (ii) take photographs and make video recordings; (iii) take samples of Defendant's raw ingredients, in-process and finished articles of food, containers, and packaging material; and (iv) examine and copy all records relating to receiving, preparing, processing, packing, holding, and distributing any and all articles of food and their components. The inspections shall be permitted upon presentation of a copy of this Order and appropriate credentials. The inspection authority granted by this Order is apart from, and in addition to, the authority to make inspections under the Act, 21 U.S.C. § 374.

11. If, at any time after entry of this Order, FDA determines, based on the results of an inspection, sample analysis, report or data prepared or submitted by Defendant, or the Expert(s), or any other information, that Defendant has failed to comply with any provision of this Order, has violated the Act or its implementing regulations, or that additional corrective actions are necessary to achieve compliance with this Order, the Act, or its implementing regulations, FDA may, as and when it deems necessary, notify Defendant in writing of the noncompliance and order Defendant to take appropriate corrective action, including, but not limited to, ordering Defendant to immediately take one or more of the following actions:

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A. Cease receiving, preparing, processing, packing, holding, and distributing any articles of food;

B. Recall, at Defendant's expense, all articles of food that have been distributed and/or are under the custody and control of Defendant's agents, distributors, customers, or consumers;

C. Revise, modify, expand, or continue to submit any reports, plans, procedures, or other records prepared pursuant to this Order;

D. Submit additional reports or information to FDA as requested;

E. Submit additional samples to a qualified laboratory for analysis;

F. Institute or re-implement any of the requirements set forth in this Order;

G. Issue a safety alert; and/or

H. Take any other corrective actions as FDA, in its discretion, deems necessary to protect the public health or bring Defendant into compliance with this Order, the Food & Drug Act, or its implementing regulations.

The provisions of this paragraph shall be separate and apart from, and in addition to, any other remedy available to FDA. Defendant shall pay all costs of recalls and other corrective actions, including the costs of FDA's supervision, inspections, investigations, analyses, examinations, sampling, testing, reviews, document preparation, travel, and subsistence expenses to implement and monitor the remedies set forth in paragraph 11, at the rates specified in paragraph 12.

12. Defendant shall pay all costs of FDA's inspections, investigations, supervision, analyses, examinations, sampling, testing, and reviews that FDA deems necessary to evaluate Defendant's compliance with any part of this Order at the standard rates prevailing at the time

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the costs are incurred. Defendant shall make payment in full to FDA within twenty (20) business days of receiving written notification from FDA of the costs. As of the date that this Order is entered by the court, these rates are: $102.39 per hour or fraction thereof per representative for inspection and investigative work; $122.71 per hour or fraction thereof per representative for analytical or review work; $0.56 per mile for travel expenses by automobile; government rate or the equivalent for travel by air or other means; and the published government per diem rate for subsistence expenses where necessary. In the event that the standard rates applicable to FDA supervision of court-ordered compliance are modified, these rates shall be increased or decreased without further order of the Court.

13. Upon receipt of any order issued by FDA pursuant to paragraph 11, Defendant shall immediately and fully comply with the terms of the order. Any cessation of operations or other action described in paragraph 11 shall be implemented immediately upon notice from FDA and shall continue until Defendant receives written notification from FDA that Defendant appears to be in compliance with this Order, the Act, and its implementing regulations, and that Defendant may resume operations. After a cessation of operations, and while determining whether Defendant appears to be in compliance with the Order, the Act, and its implementing regulations, FDA may require Defendant to re-institute or re-implement any of the requirements of this Order.

14. Defendant shall promptly provide any information or records to FDA upon request regarding the receiving, preparing, processing, packing, labeling, holding, and/or distributing of Defendant's products. Defendant shall maintain copies of her HACCP plans, along with copies of all records required by such plans, 21 C.F.R. Part 123, or this Order, at Defendant's facility, and any other location(s) at or from which Defendant receives, prepares, processes, packs, holds,

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and/or distributes articles of food, in a location where such records are readily available for reference and inspection by FDA. Defendant shall retain all records referred to in this paragraph for at least three (3) years after the date the records are prepared.

15. Within five (5) calendar days after entry of this Order, Defendant shall prominently post a copy of this Order (in English and any other language necessary to effectively convey the substance of the Order) in a conspicuous location near the front door of Defendant's facility, so that it is visible to anyone entering the property and shall ensure that the Order remains posted for as long as the Order remains in effect. Within ten (10) business days after entry of this Order, Defendant shall provide to FDA an affidavit, from a person with personal knowledge of the facts stated therein, stating the fact and manner of compliance with this paragraph.

16. Within ten (10) calendar days after entry of this Order, Defendant shall hold a general meeting or series of smaller meetings for all Associated Persons, at which she shall describe the terms and obligations of this Order (in English and any other language necessary to effectively convey the substance of the Order). Within fifteen (15) business days after entry of this Order, Defendant shall provide to FDA an affidavit, from a person with personal knowledge of the facts stated therein, stating the fact and manner of compliance with this paragraph and a copy of the agenda, list of attendees, and meeting minutes from the meeting(s) held pursuant to this paragraph.

17. Within ten (10) calendar days after entry of this Order, Defendant shall provide a copy of the Order by personal service or certified mail (return receipt requested) to each and all of her Associated Persons and any and all persons in active concert or participation with her (including individuals, directors, corporations, subsidiaries, affiliates, and partnerships). Within thirty (30) calendar days after entry of this Order, Defendant shall provide to FDA an affidavit,

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from a person with personal knowledge of the facts stated therein, stating the fact and manner of compliance with this paragraph, identifying the names, addresses, and positions of all persons so notified, and attaching a copy of the executed certified mail return receipts.

18. Defendant shall notify FDA in writing at least ten (10) business days before any change in ownership, name, or character of her business that occurs after entry of this Order, including an incorporation, reorganization, creation of a subsidiary, relocation, dissolution, bankruptcy, assignment, lease, sale, or any other change in the structure or identity of Felix Custom Smoking or the assignment, lease, or sale of any business assets, such as buildings, equipment, or inventory, that may affect obligations arising out of this Order. Defendant shall provide a copy of this Order to any prospective successor or assign at least twenty (20) business days prior to any sale or assignment. Defendant shall furnish FDA with an affidavit of compliance with this paragraph no later than ten (10) business days prior to such assignment or change in ownership.

19. If Defendant fails to comply with the provisions of this Order, the Act, and/or its implementing regulations, then Defendant shall pay to the United States of America liquidated damages in the sum of two thousand dollars ($2,000) for each day that Defendant fails to comply with this Order, the Act, and/or its implementing regulations; an additional sum of one thousand dollars ($1,000) in liquidated damages per day for each violation of this Order, the Act, and/or its implementing regulations; and an additional sum equal to twice the retail value of each shipment of adulterated fish or fishery product. The liquidated damages specified in this paragraph are not punitive in nature and their imposition does not in any way limit the ability of the United States to seek, and the Court to impose, additional criminal or civil penalties based on conduct that may also be the basis for payment of the liquidated damages.

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20. Should the United States bring and prevail in a contempt action to enforce the terms of this Order, Defendant shall, in addition to other remedies, reimburse the United States for its attorneys' fees (including overhead), expert witness fees, travel expenses incurred by attorneys and witnesses, investigational and analytical expenses, administrative and court costs, and any other costs or fees relating to such contempt proceedings.

21. All decisions specified in this Order shall be vested in the discretion of FDA. Defendant shall abide by the decisions of FDA, and FDA's decisions shall be final and, to the extent that these decisions are subject to review, shall be reviewed by the Court under the arbitrary and capricious standard set forth in 5 U.S.C. § 706(2)(A). Review by the Court of any FDA decision rendered pursuant to this Order shall be based exclusively on the written record before FDA at the time of the decision. No discovery shall be taken by either party.

22. Defendant shall address all communications required under this Order to the Director, Seattle District Office, 22215 26th Avenue Southeast, 210, Bothell, WA 98021. All such communications to FDA required by the terms of this Order shall reference this civil action by case name and civil action number and shall be prominently marked "Order Correspondence."

23. Except as provided in the foregoing provisions of this Order, the parties shall bear their own costs and attorneys' fees in this action.

24. If Defendant has continuously complied with the terms of this Order, the Act, and all applicable laws and regulations for a period of five (5) years after entry of this Order, Defendant may petition this Court for relief from this Order. If, at the time of the petition, in FDA's judgment Defendant has met the foregoing criteria, Plaintiff will not oppose such petition.

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25. This Court retains jurisdiction over this action and the parties thereto for the purpose of enforcing and modifying this Order and for the purpose of granting such additional relief as may be necessary or appropriate.

DATED this 15th day of March, 2023.

UNITED STATES DISTRICT JUDGE
The Honorable Tana Lin

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